

State Operations Manual

Appendix D - Guidance to Surveyors: Portable X-Ray Services - (Rev. 1, 05-21-04)

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In view of the inherent danger in the use of X-rays, especially when they are being used without the direct personal supervision of a physician, strict standards have been set up for coverage of portable X-rays under the Medicare program. Accordingly, suppliers must meet all standards in each condition to qualify. **In other words, if one standard is not met, the supplier of portable X-ray services must be certified as not in compliance with the Conditions for Coverage.** Coverage services are defined in Regulation 42 CFR 405.1401(c).

§405.1411 Condition for Coverage: Compliance With Federal, State and Local Laws

The supplier, its equipment and personnel must be licensed or registered in accordance with applicable Federal, State and local laws. Review licenses and registration permits to confirm their validity and currency.

X-ray equipment manufactured on or after August 1, 1974 must bear a label indicating it meets FDA standards. If equipment found in use is different from what was described to the SA prior to survey, note the name of the manufacturer, equipment model number, serial number, and date of manufacturer (if shown) so that this can be checked out after the survey. Do not show a deficiency unless it has been definitely ascertained that the equipment does not meet FDA standards.

§405.1412 Condition for Coverage: Supervision by a Qualified Physician

The performance of X-ray tests is subject to the supervision of a physician qualified by advanced training and experience in use of diagnostic X-rays regardless whether the physician owns the equipment or not. In the event the supervising physician is not listed as the owner and the physician certification required in Standard (a) has not been submitted with the Request for Approval, CMS-1880, request such certification at survey. Since Standard (a) requires an annual certification by a supervising physician if he is not the owner, ask the supplier to have the certification for the current year available at the time of survey to prevent any delay in certification (see Exhibit 1C.)

To confirm that a physician-supervisor specializes in radiology and is recognized by the medical community as a specialist in radiology (Standard (b)), the record should reflect that the physician is

- (1) Board certified or board eligible in radiology;
- (2) Board certified or board eligible in a medical specialty which includes advanced training in use of X-rays, e.g., The American Board of Orthopedic Surgery, the American Board of Internal Medicine, The American Board of Physical Medicine and Rehabilitation and The Board of Thoracic Surgery, or
- (3) Recognized by the medical community as a specialist in radiology. Check the American Medical Directory or the Dictionary of Medical Specialists for (1) and (2).

To substantiate (3), the record should show how much of the physician's practice is devoted to radiology as well as what other specialties he practices, and the basis for recognition as a specialist by the medical community; i.e., do other physicians regularly refer radiology work to him, and does he have arrangements with local hospitals to provide radiology services or act as a radiology consultant.

§405.1413 Condition for Coverage: Qualifications and Orientation of Technical Personnel and Employee Records

Diplomas, resumes, and other records maintained by the supplier or where applicable, in State licensure records, show that a particular academic or training requirement has been met. In the absence of such documentary evidence, request that the individuals involved arrange to have the school or physician involved in attesting to the academic or experience qualifications mail this documentation directly to the SA. Ascertain the methods of staff member orientation and also check the procedural manual for content to ensure that it includes all factors cited in the Survey Report.

If a supplier uses the services of a non-physician equipment operator, interview that individual to assess his/her functions, duties, responsibilities and the degree of

supervision he/she receives. Review policies and procedures, records of examinations the operator has taken, and records and reports of inspections of equipment.

§405.1414 Conditions for Coverage: Referral for Services and Preservation of Records

The supplier's records showing that a physician ordered X-ray tests in writing licensed to practice in the State are essential to establish that the standards are met. Follow up within a reasonable period (i.e., 90 days) to recheck the supplier's records for compliance with this important standard.

While §405.1414(a)(2) is explicit as to the type of information that is required in a physician's request, there may be some leeway granted in initial survey in this area. If all pertinent information has been furnished to the supplier, but was simply not retained or recorded by the supplier, the standard may be considered as met. However, inform the supplier of the need in the future to obtain specific data as cited in the regulations. This leeway is to be granted only temporarily, and is not to be interpreted as relaxation of the requirement that all standards must be met. The supplier's patient records should be checked for the information specified in §405.1414(b). If past records are not consistently complete as to the required data, the supplier should be informed of the need to establish a system of record keeping that will conform to the regulations. If it is found that no records have been kept, the supplier should be informed that a recheck would be made in 30 days to insure that it is in compliance with this requirement. The surveyor should inform the supplier of the need for keeping records for a period of at least 2 years, or for the period of time required by State law, whichever is longer.

§405.1414 Condition for Coverage: Safety Standards

Each of the eleven safety standards, if applicable, must be met to find a supplier in compliance. Where a State or local radiation health inspection program conducted a survey within 12 months of the Medicare survey and such inspection reveals compliance with all applicable safety standards, such State or local investigation will satisfy initial compliance with this regulation. However, if any equipment, operating procedures, or shielding was noted as constituting a potential hazard, it must be corrected before recommending approval. Also, if the State inspection did not completely cover each applicable standard, the inspection report is acceptable only for that portion covered and the surveyor would be responsible for evaluating the pertinent standards not covered in the previous inspection.

Where deficiencies are found to exist at the time of survey, the supplier should be informed that corrective action is necessary within 30 days and that he must submit proof that correction has been made.

§405.1416 Condition for Coverage: Inspection of Equipment

If State records or suppliers records fail to indicate that State or local radiation health inspection have been performed within 24 months of the Medicare survey, the survey for Medicare purposes of the supplier by a qualified inspector will satisfy this requirement.